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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,706	08/23/2001	Tetsuya Ishikawa	029650-103	9286

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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,706	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the amendment filed July 2, 2004. **Claims 1-20** are currently pending and are under examination.

Priority

The current application filed on August 23, 2001 is a CIP of application 09/507,691 filed on February 22, 2000, which in turn claims priority to foreign application, Japan 11-041913 filed on February 19, 1999 and foreign application, Japan 11-311364 filed on November 11, 1999. A certified translation of foreign documents Japan 11-041913 and Japan 11-311364 have not been provided.

Withdrawal of Objections and Rejections

The rejection of **claims 2, 4, 6, 8, 15,18 and 20** under 35 U.S.C § 112, second paragraph is withdrawn.

The rejection of **claims 1-17** under 35 U.S.C § 101 as being drawn to non-statutory subject matter is withdrawn.

The rejection of **claim 1, 3, 5, 7 and 15-17** under 35 U.S.C § 102(b) as being anticipated by Hashi et al. is withdrawn.

The rejection of **claims 9-13** under 35 U.S.C § 103(a) as being unpatentable over Hashi et al. in view of Tuan is withdrawn.

The rejection of **claims 1-8 and 18** under 35 U.S.C § 103(a) as being unpatentable over Hashi et al. in view of Irani is withdrawn.

The rejection of **claims 19-20** under 35 U.S.C § 103(a) as being unpatentable over Hashi et al. in view of Geistlich et al. is withdrawn.

New rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 5, 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In **claims 2, 4, 5, 8** the applicants cite a protease hydrolysis fragment of fibronectin without providing sufficient information in regards to the written description of the mentioned fragment. A protease hydrolysis fragment of fibronection can comprise a variety of amino acid residues depending on the efficiency of the hydrolysis of the peptide hence giving rise to a multiplicity of peptides with different lengths and characteristics, the applicants have not provided written description as to which of these fragments will bind collagen after the hydrolysis procedure is performed. In order for the applicants to provide adequate written

description for the mentioned fragments, the applicant must provide the amino acid sequences of the peptide fragments or other characteristics such as percentage homology in view of the ability to bind collagen after hydrolysis step.

Claims 2, 4, 6, 8, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claims 2, 4, 6 and 8** the term "corresponds" allows for a multiplicity of interpretations. For example, corresponds in this case, could mean; a polypeptide that has a high degree of homology to the original, a polypeptide that comprises the original, or a polypeptide that resembles the original in regards to structural integrity.

Regarding **claim 15**, the phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12-14 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballance et al.

Ballance et al. disclose a hybrid polypeptide comprising of a first peptide that is 99% identical to amino acid residues 2-341 of amino acid sequence designated as SEQ ID No: 1 (amino acid residues 260-598 of SEQ ID No:16 of United States Patent 5,766,883) and a second peptide that has human serum albumin activity (HSA). (Column 1, line 38-52 and examples 2-3). Ballance et al. disclose further that sites providing for enzymatic or chemical cleavage can be provided either by appropriate juxtaposition of the N-terminal and C-terminal portions or by the insertion there between of an appropriate linker (column 6, lines 4-9, examples 2-3) **(present claims 1-8, and 12-14)**. Ballance et al. also teach that the product of invention can be produced in bacteria (examples 1-3), used for wound healing and can be topically applied (column 5, lines 60-65) **(present claims 16-18**.)

Thus Ballance et al. teach all the elements of **claims 1-8, 12-14 and 16-18** and these claims are anticipated under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballance et al. in view of Tuan et al. (cited in IDS filed August 23, 2003).

Ballance et al. disclose a polypeptide construct as mentioned above. Ballance et al. do not explicitly teach that the second peptide that is fused on the carboxyl terminal side of said first peptide is a cytokine or a growth factor.

Tuan et al. disclose a hybrid construct that comprises a spacer with a proteolytic site, a first peptide with collagen binding activity and a second peptide that is a cytokine. Tuan et al. further disclose that the cytokine of the mentioned hybrid construct is a growth factor and is fused on the carboxyl side of the first peptide (materials and methods, figure 1) (**present claims 9-12**). Tuan et al. also disclose that the carboxyl end of the amino acid spacer used in their construct is a proteolytic site (Figure 1) (**present claim 14**).

The Transforming Growth Factor beta (TGF-β) super family is a large group of cytokines that exert profound influences on the physiology of wound healing. Numerous animal studies have demonstrated the efficiency of exogenous (TGF-β) in promoting wound healing, the treatment of diabetic ulcers, and burns. However, clinical interest in the use of such cytokines as therapeutic agent has been hampered by the limited availability of such proteins. Genetic engineering and expression of such proteins in E.

coli followed by purification and renaturation allows for a useful method of obtaining such cytokines.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a biological hybrid protein that could have been genetically engineered for the advantages of ease of purification. A collagen-binding domain can be used to attach the hybrid product to the desired chromatography matrix, a proteolytic spacer allows for the release of the desired cytokine and, since most proteases cleave the carboxyl terminal of the recognition sequence when the protease recognition sequence is added on the amino terminal of the cytokine, no excessive sequence would be left on the amino terminal of the cytokine after the cleavage by the protease as taught by Ballance et al. and Tuan et al. see Tuan et al at (materials and methods, figure 1).

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballance et al. United States Patent Number 5,766,883 in view of Geistlich et al. US Patent 5,837,278. **Claims 19-20** are further limitations of **claim 1** that cite a biomaterial comprising a composite wherein the collagen-binding physiologically active polypeptide of **claim 1** is combined with collagen. Ballance et al. and do not disclose biomedical material comprising a composite wherein a collagen-binding physiologically active hybrid polypeptide is combined with collagen. Geistlich et al. disclose a biomaterial comprising collagen. Collagen is useful as a biomaterial for use in tissue regeneration and wound repair. It has been shown that collagen is especially beneficial in guided tissue regeneration after such procedures as orafacial and dental surgery. In such

situations it is often important for bone regeneration to begin taking place immediately after the surgical procedure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a biomaterial consisting of collagen and a collagen-binding polypeptide construct comprising a peptide having collagen binding activity wherein the said peptide is connected to a second peptide having physiological activity different from fibronectin activity, for the advantages of an efficient wound healing biomaterial that could be used in procedures such as dental surgery wherein tissue repair and bone regeneration are of utmost importance as taught by Ballance et al. and Geistlich see Geistlich et al. at (claim 1 of patent 5,837,278)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-6, 9-14 and 16-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/344,634. Although the conflilicting calims are not identical, they are not patentably distinct from each other because the claims of

both copending applications are drawn to a hybrid polypeptide that comprises the collagen-binding domain of fibronectin ligated with or without a spacer to a functional acell growth factor or a cytokine. The claims aredrawn to a biomaterial containing a functional polypeptide/collagen composite. Furthermore , claims 4-5 in copending application 10/344,634 is claiming a polypeptide produced by recombinant DNA technology, which is currently being claimed in the present application.
This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RR

Robert B. Mondesi
Patent Examiner
Group 1653
09-18-09

ROBERT A. WAX
PRIMARY EXAMINER